

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In te application of: Meyers, William E..

Serial No.: 09/679,970 Filed: 10/05/2000 Art Unit: 3625

Examiner: Sugarman, S.

For: Method of Manufacture of Contact Lens to Treat Vision

Assistant Commissioner for Patents Washington, D.C. 20231

DECLARATION OF PRIOR INVENTION IN THE UNITED STATES OR IN A NAFTA OR WTO MEMBER COUNTRY TO OVERCOME CITED PATENT OR PUBLICATION (37 C.F.R. 1.131)

PURPOSE OF DECLARATION

- 1. This declaration is to establish completion of the invention in this application in the United States, at a date prior to July 7, 1999, that is the effective date of the prior U.S. Patent Nos. 6,176,579 and 6,364,482 that were cited by the examiner.
- 2. William E. Meyers, the person making this declaration, is an inventor of the present invention.

FACTS AND DOCUMENTARY EVIDENCE

3. To establish the date of completion of the invention of this application, the following attached documents and/or models are submitted as evidence:

Exhibit A: Exhibit A; A printout of computer files dated prior to the date of July 7, 1999, being the effective date of U.S. Patent Nos. 6,176,579 and 6,364,482 referred to above. The computer files relate to the conception of a corneal contact lens for reshaping of the cornea in corneal refractive therapy, wherein the lens was conceived to include a central zone having a radius, r_c , a landing zone having a radius, r_l , with these zones connected by an "S" curve. In the design of the conceived lens, the "S" curve as contemplated was an annular zone and integral with the central zone and landing zone. To match the curvatures of the central and leading zones, the origin of the curvature of the "S" curve zone required that it be non-coaxial to the origin of the central zone curve. The actual date of conception has been redacted from the document.

REDUCTION TO PRACTICE IN U.S. OR NAFTA OR WTO MEMBER COUNTRY

4. As evidenced by the attached Exhibit A, the invention in this application was conceived in the United States. The invention was documented and further developed, with information relating to such further development attached as Exhibit B, which also is dated prior to the date of July 7, 1999. The invention was thereafter disclosed to a patent attorney for the purpose of conducting a patentability search on the invention in preparation for a subsequent patent application relating to the invention.

(Declaration of Prior Invention in the United States or in a NAFTA or WTO Member Country to Overcome Cited Patent or Publication--37 C.F.R. 1.131Xpage 1 of 1) The invention was thereafter constructively reduced to practice in the United States by the filing of U.S. provisional patent application No. 60/214,554 on June 27, 2000 relating to a particular lens for corneal refractive therapy, and the instant application Serial No. 09/679,970 filed October 5, 2000.

DILIGENCE

5. The following is a statement establishing the diligence of the applicant, from the time of his conception, to a time just prior to the date of the reference, up to the date of constructive reduction to practice by the filing of U.S. Provisional Application no. 60/214,554 on June 27, 2000 and the instant patent application 09/679,970 on October 5, 2000.

The current invention was conceived at an earlier date than the cited art, as evidenced by the attached Exhibit A. The invention was then disclosed to a patent attorney, Scott M. Oldham, for the purpose of assessing patentability and preparation of a patent application on April 10, 2000. Thereafter, a search was conducted of the patent literature ad various patents were noted. Further research relating to the patent literature was initiated at that time, and preparation of a patent application was initiated by patent counsel, Scott M. Oldham. Based upon the foregoing, from a date just prior to July 7, 1999, and continuing until June 27, 2000, and until October 5, 2000, the subject matter of the invention was in the process of being further developed and prepared as a patent application by patent counsel for the applicant. The initial prepared patent application was filed by patent counsel on June 27, 2000, and a further application filed on October 5, 2000, being the current application Serial No. 09/679,970.

TIME OF PRESENTATION OF THE DECLARATION

6. This declaration is submitted prior to final rejection.

DECLARATION

7. As a person signing below:

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

SIGNATURE(S)

William E. Meyers

Inventor's signature

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(Declaration of Prior Invention in the United States or in a NAFTA or WTO Member Country to Overcome Cited Patent or Publication--37 C.F.R. 1.131Xpage 2 of 2)

EXHIBIT A

 $r_c := 7.8 \cdot mm$

 $r_1 := 8.5 \cdot mm$

 $r_e := 17 \cdot mm$

r_c=radius of the central base curve r_I=radius of the landing zone re=radius of the edge curve y_c=elevation versus x for the central base curv y_s=elevation versus x for the "S"curve y_l=elevation versus x for the landing zone curv a,b,c= computed parameters for the "S" curve

$$y_c := \sqrt{r_c^2 - (x \cdot mm)^2}$$

for x=0...x=oz

$$y_s := a \cdot (x)^3 + b \cdot (x)^2 + c \cdot x$$
 for x=oz...x= oz+"S" width

$$y_{l} := \sqrt{r_{l}^{2} - \left(x \cdot mm\right)^{2}}$$

for x=oz+"S" width to oz+"S" width+ landing zone width

$$y_l := \sqrt{r_e^2 - (x \cdot mm)^2}$$

for x= oz+"S" width+ landing zone width to diameter/2

The equations below and their derivatives represent the equations for the base curve (b) and the S curve (s) and the angle (a). The junctions between the Base Curve and the S curve $(x_{j2},y_{j2}xx)$ and the bottom of the box W mm wide and L mm deep i.e. $(x_{j1}+W,y_{j1}-L)$ are used to define A,B,and C by equating the slopes at those two points and choosing a point in the box through which the S passes. This point (x_m,y_m) is defined to be half way down the box and 1/3 of the way from the side closest to center toward to other side i.e. $(x_{j1}+W/3,y_{j1}-L/2)$. The following values must be given:

 $r_h := 7.8$ The base curve of the central zone

M := -1 The slope of the landing zone

W := 1 The width of the S curve

L := .05 The length or depth of the S curve

 $J_1 = 3$ Radial distance from the center of the lens to the junction of the base curve and S curve

The equation for the S curve is:

$$y_s := A \cdot x^3 + B \cdot x^2 + C \cdot x$$

The derivative is:

$$\frac{d}{dx}(y_s) = 3 \cdot A \cdot x^2 + 2 \cdot B \cdot x + C$$

The Equation for the base curve is:

$$y_b := \sqrt{r_b^2 - x^2}$$

The derivative of the base curve equation is:

$$\frac{\mathrm{d}}{\mathrm{d}x}y_{\mathrm{b}} = \frac{-1}{\sqrt{r_{\mathrm{b}}^2 - x^2}} \cdot x$$

The junction of the base curve and the S curve is at radius J_1 thus J_1 is the x value at the junction:

$$x_{i1} := J_1$$

The y value at that junction may then be calculated from the x value and the base curve equation:

$$y_{j1} := \sqrt{r_b^2 - x_{j1}^2}$$

Since the S curve is described as having width W and length L. The x value of the junction at the other end of the S curve can be obtained by adding the width of the S curve to the x value at the first junction:

$$x_{i2} := x_{i1} + W$$

Similarly the y value at J_2 can be derived by adding the vertical length of the S curve to the y value of the first junction:

$$y_{i2} := y_{i1} - L$$

A mid point has been chosen to complete the description of the S curve, it is half way down in the - y direction toward the J_2 point and one third of the way in the +x direction from J_1 to J_2 . Thus the x value of this mid point is given by:

$$x_m := x_{j1} + \frac{W}{3}$$

And the y value is given by:

$$y_m := y_{j1} - \frac{L}{2}$$

The simple equation (see below) for the flat landing zone requires a slope M to be given but the "intercept" can be derived from the following relationship since point x_{j2} , y_{j2} is known.

$$D := y_{j2} - M \cdot x_{j2}$$

The equation for the flat landing zone is:

$$y_a := M \cdot x + D$$

The slope of the landing zone is given by M

$$\frac{\mathrm{d}}{\mathrm{d}\mathbf{s}}y_{\mathbf{a}'}=\mathbf{M}$$

The following 3 equations relate to the S curve and may be used to solve for the 3 constants A,B,C

The first simply requires the S curve to pass through the a mid point whose exact position has been chosen to assure gradual transition into the landing zone.

$$y_m = A \cdot x_m^3 + B \cdot x_m^2 + C \cdot x_m$$

The second equation imposes that the slope of the "S" curve be identical to that of the basecurve at the first junction:

$$3 \cdot A \cdot x_{j1}^2 + 2 \cdot B \cdot x_{j1} + C = \frac{-1}{\sqrt{r_b^2 - x_{j1}^2}} \cdot x_{j1}$$

The third equation requires that the slope of the S curve be identical to the flat landing zone at their junction:

$$3 \cdot A \cdot x_{j2}^2 + 2 \cdot B \cdot x_{j2} + C = M$$

These three simultaneous equations may be solved by substitution to give the three solutions below for A,B and C.

$$A := \frac{-\left[2 \cdot J_{1} \cdot y_{m} \cdot \left(y_{j1}\right) - 2 \cdot J_{1} \cdot M \cdot x_{m} \cdot \left(y_{j1}\right) - 2 \cdot x_{j2} \cdot y_{m} \cdot \left(y_{j1}\right) + M \cdot x_{m}^{2} \cdot \left(y_{j1}\right) + J_{1} \cdot x_{m}^{2} - 2 \cdot J_{1} \cdot x_{m} \cdot x_{j2}\right]}{\left[\left(3 \cdot J_{1}^{2} \cdot x_{m} - 6 \cdot J_{1}^{2} \cdot x_{j2} - 2 \cdot J_{1} \cdot x_{m}^{2} + 6 \cdot J_{1} \cdot x_{j2}^{2} - 3 \cdot x_{j2}^{2} \cdot x_{m} + 2 \cdot x_{j2} \cdot x_{m}^{2}\right) \cdot \left[\left(y_{j1}\right) \cdot x_{m}\right]\right]}$$

$$A = 0.148$$

$$B := \frac{-\left(y_m - A \cdot x_m^3 + 3 \cdot x_m \cdot A \cdot x_{j2}^2 - x_m \cdot M\right)}{\left(-x_m^2 + 2 \cdot x_m \cdot x_{j2}\right)}$$

$$B = -1.8$$

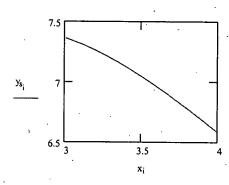
$$C := -3 \cdot A \cdot x_{j2}^2 - 2 \cdot B \cdot x_{j2} + M$$
 $C = 6.65$

To graph the S curve the following 3 range variables are defined

$$i := 1..100$$

$$x_i := 3 + \frac{1}{100} \cdot i$$

$$y_{s_i} := A \cdot (x_i)^3 + B \cdot (x_i)^2 + C \cdot x_i$$



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$$\frac{-\left[2\cdot x_{j1}\cdot y_{m}\cdot \left(y_{j1}\right)-2\cdot x_{j1}\cdot M\cdot x_{m}\cdot \left(y_{j1}\right)-2\cdot x_{j2}\cdot y_{m}\cdot \left(y_{j1}\right)+M\cdot x_{m}^{2}\cdot \left(y_{j1}\right)+x_{j1}\cdot x_{m}^{2}-2\cdot x_{j1}\cdot x_{m}\cdot x_{j2}\right]}{\left[\left(3\cdot x_{j1}^{2}\cdot x_{m}-6\cdot x_{j1}^{2}\cdot x_{j2}-2\cdot x_{j1}\cdot x_{m}^{2}+6\cdot x_{j1}\cdot x_{j2}^{2}-3\cdot x_{j2}^{2}\cdot x_{m}+2\cdot x_{j2}\cdot x_{m}^{2}\right)\cdot \left[\left(y_{j1}\right)\cdot x_{m}\right]\right]}=0.148$$